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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE SUSAN ILLSTON, JUDGE

ARIOSA DIAGNOSTICS, INC., )

PLAINTIFF, )

VS. )

SEQUENOM, INC., )

DEFENDANTS. )

ARIOSA DIAGNOSTICS, INC., )

COUNTERCLAIM-DEFENDANT, )

VS. )

ISIS INNOVATION LIMITED, )

NOMINAL COUNTERCLAIM )

DEFENDANT, )

TRANSCRIPT OF PROCEEDINGS

TRANSCRIBED BY: KATHERINE WYATT, CERTIFIED REPORTER

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1 FOR PLAINTIFF:

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5  
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8 **BY: MICHAEL J. MALECEK, ESQUIRE**  
**ATON ARBISSER, ESQUIRE**  
**LILY R. ROBINTON, ATTORNEY AT**  
9 **LAW**

10 **FOR NOMINAL COUNTERCLAIM DEFENDANT:**

11 **SATTERLEE STEPHENS BURKE BURKE**

12 230 PARK AVENUE

13 NEW YORK, NEW YORK 10169

14 **BY: MARIO AIETA, ESQUIRE (BY PHONE)**  
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OCTOBER 11, 2013

9:30 O'CLOCK A.M.

**P R O C E E D I N G S**

THE CLERK: CALLING CIVIL 11-6391, ARIOSIA VERSUS SEQUENOM.

MR. GINDLER: GOOD MORNING, YOUR HONOR. DAVID GINDLER OF IRELL & MANELLA FOR THE PLAINTIFF ARIOSIA DIAGNOSTICS. AND WITH ME IS MY PARTNER, ANDREI IANCU.

MR. MALECEK: GOOD MORNING, YOUR HONOR. MIKE MALECEK FROM KAYE SCHOLER ON BEHALF OF SEQUENOM .

WITH ME IS ATON ARBISSER AND OUR COLLEAGUE IS LILY ROBINTON.

BUT WE NEED TO GET SOMEBODY ON THE PHONE.

THE COURT: WHILE WE'RE DOING THAT, SEQUENOM, I RECEIVED THIS IN THE MAIL. IT IS NOT READ BY MY JUDICIAL EYES, SO I DON'T REALLY KNOW WHAT IS IN IT. BUT IT LOOKS TO ME LIKE IT HAS NOTHING TO DO WITH MY JOB IN THIS CASE, BUT IT RELATES TO SEQUENOM.

SO I'M JUST GOING TO GIVE IT TO YOU, AND YOU SHOULD PROBABLY SHOW IT TO ARIOSIA AND SEE IF THEY THINK IT RELATES TO THE CASE. IT WAS NOT FILED. IT JUST CAME IN THE MAIL. SO IF ANYBODY WANTS TO FILE ANY PART OF IT, GO FOR IT. BUT I DON'T THINK THAT IT'S IN THE CASE.

MR. MALECEK: YOU DIDN'T RECEIVE THIS FROM US, I DON'T

1 THINK.

2 THE COURT: OH, NO. NO. NO. THERE'S AN ADDRESS ON THERE.  
3 I DON'T REMEMBER WHO SENT IT. IT WAS NOBODY RELATED TO THE  
4 CASE.

5 (THEREUPON, A PHONE CALL IS PLACED BY CLERK.)

6 MR. AIETA (BY PHONE): GOOD AFTERNOON.

7 THE CLERK: IS THIS MARIO AIETA?

8 MR. AIETA (BY PHONE): IT IS.

9 THE CLERK: IT'S TRACY WITH JUDGE ILLSTON'S CHAMBERS.

10 MR. AIETA (BY PHONE): GOOD MORNING.

11 THE CLERK: COULD YOU JUST STATE YOUR APPEARANCE FOR THE  
12 RECORD? WE'VE ALREADY CALLED THE CASE.

13 MR. AIETA (BY PHONE): SURE. THIS IS MARIO AIETA OF  
14 SATTERLEE STEPHENS BURKE BURKE FOR ISIS INNOVATION.

15 THE CLERK: THANK YOU.

16 THE COURT: GOOD MORNING, SIR.

17 MR. GINDLER: GOOD MORNING.

18 THE COURT: AND HERE, IT LOOKS LIKE THERE'S A LITTLE BIT  
19 MORE OF THAT.

20 THE CLERK: HERE, THERE'S --

21 THE COURT: SO WE HAVE ON TODAY CROSS MOTIONS FOR SUMMARY  
22 JUDGMENT RELATED TO WHETHER OR NOT THE '540 PATENT IS DRAWN TO  
23 PATENT-ELIGIBLE SUBJECT MATTER UNDER 35 U.S.C. 101, WHICH WE  
24 HAVE LOOKED AT WITH SOME CARE. AND THIS APPEARS TO BE A HOT  
25 AREA IN THE LAW RIGHT NOW.

1 AND I HAVE, FRANKLY, GONE BACK AND FORTH AND BACK AND  
2 FORTH ON WHAT TO DO WITH THIS MOTION. MY CURRENT THINKING,  
3 I'LL TELL YOU, FOR THE BOTTOM LINE IS TO FIND THAT IT IS  
4 PATENT-ELIGIBLE.

5 SO THAT'S, I GUESS, DENYING ARIOSAS MOTION AND GRANTING  
6 SEQUENOM'S. BUT I THINK IT'S A VERY, VERY CLOSE QUESTION. AND  
7 I WILL BE HAPPY TO HEAR FROM YOU ABOUT IT.

8 ONE -- WELL, I'LL BE HAPPY TO HEAR FROM YOU ABOUT IT. I  
9 DON'T CARE WHO GOES FIRST.

10 MR. GINDLER: GOOD MORNING, YOUR HONOR.

11 THE ANSWER TO THE QUESTION, OF COURSE, DEPENDS UPON THE  
12 QUESTION THAT YOU ASK FOR PATENT-ELIGIBLE SUBJECT MATTER.

13 AND I THINK THE SUPREME COURT HAS DONE A GOOD JOB OF  
14 LAYING OUT WHAT THE CENTRAL INQUIRY IS. THAT WAS DONE FOR  
15 METHOD CLAIMS, IN PARTICULAR, IN THE LIFE SCIENCES AREA IN THE  
16 MAYO VERSUS PROMETHEUS CASE, WHERE THE COURT NOTES THAT ITS  
17 PRIOR PRECEDENCE INSISTS THAT A PROCESS THAT FOCUSES UPON THE  
18 USE OF A NATURAL LAW ALSO CONTAIN OTHER ELEMENTS OR COMBINATION  
19 OF ELEMENTS, SOMETIMES REFERRED TO AS AN INVENTIVE CONCEPT,  
20 SUFFICIENT TO ENSURE THAT THE PATENT AMOUNTS TO SIGNIFICANTLY  
21 MORE THAN A PATENT UPON THE NATURAL LAW ITSELF.

22 WHAT'S IMPORTANT ABOUT THAT IS THAT THE INVENTIVE CONCEPT  
23 RELATES TO THE OTHER ELEMENTS, NOT THE NATURAL LAW, BUT WHAT  
24 ELSE THE INVENTOR BROUGHT TO THE TABLE.

25 THE COURT: RIGHT. AND SO --

1 MR. GINDLER: SO SAID A DIFFERENT WAY, AGAIN, LOOKING AT  
2 THE MAYO VERSUS PROMETHEUS CASE, THE UNDERLYING FUNCTIONAL  
3 CONCERN HERE IS A RELATIVE ONE.

4 HOW MUCH FUTURE INNOVATION IS FORECLOSED RELATIVE TO THE  
5 CONTRIBUTION OF THE INVENTOR? WHAT'S IMPORTANT IS THAT THE  
6 CONTRIBUTION OF THE INVENTOR IS NOT ASSESSED RELATIVE TO THE  
7 NATURAL PHENOMENON OR THE NATURAL LAW.

8 AND THAT POINT WAS MADE CLEAR NOT JUST IN MAYO VERSUS  
9 PROMETHEUS BY POINTING OUT YOU LOOK AT THE OTHER ELEMENTS.  
10 THAT COMES FROM PRIOR SUPREME COURT PRECEDENCE, SUCH AS PARKER  
11 VERSUS FLOOK.

12 AND PARKER VERSUS FLOOK SAYS THAT YOU PUT THE FORMULA --  
13 IN THAT CASE IT WAS A MATHEMATICAL FORMULA -- TO THE SIDE. AND  
14 THE COURT SAID PUTTING THAT MATHEMATICAL FORMULA TO THE SIDE,  
15 THERE WAS NO INVENTIVE CONCEPT IN THE CLAIMED APPLICATION OF  
16 THE FORMULA.

17 AND THE COURT, AGAIN, IN PARKER VERSUS FLOOK SAID THE  
18 CLAIM MUST BE, QUOTE:

19 "CONSIDERED AS IF THE PRINCIPLE OR MATHEMATICAL  
20 FORMULA WERE WELL-KNOWN."

21 THE THING WHICH IS TOUTED BY SEQUENOM AND WHICH IS TOUTED  
22 BY THE APPLICANTS IN THEIR PATENT APPLICATION, AND IN THE  
23 PATENT ITSELF IS THE DISCOVERY OF A NATURAL PHENOMENON.

24 THE COURT: WELL, THEY SAY NOBODY EVER TESTED MATERNAL  
25 SERUM BEFORE. THEY THREW IT AWAY. SO WHAT IS NEW IS WE TEST

1 THE MATERNAL SERUM AND COUNT THESE THINGS.

2 MR. GINDLER: THEY ABSOLUTELY CLAIM THAT THEY WERE THE  
3 FIRST PEOPLE TO HAVE LOOKED AT MATERNAL SERUM OR PLASMA AND  
4 DETECT CELL-FREE FETAL DNA.

5 THE QUESTION IS: WHAT DID THEY BRING TO THE TABLE? WHAT  
6 IS CLAIMED IN THE PATENT OTHER THAN THE DISCOVERY OF A NATURAL  
7 PHENOMENON? BECAUSE THAT'S HOW YOU ASSESS WHETHER OR NOT YOU  
8 HAVE PATENT-ELIGIBLE SUBJECT MATTER FOR A PATENT THAT FOCUSES  
9 ON THE USE OF A NATURAL PHENOMENON.

10 IF THE DISCOVERY OF A NATURAL PHENOMENON, A NEW ONE, WERE  
11 THE HALLMARK OF PATENTABILITY, THEN THEY WOULD ALL BE  
12 PATENTABLE. EVERY TIME SOMEONE IDENTIFIES A NEW NATURAL  
13 PHENOMENON, COMES UP WITH A NEW MATHEMATICAL PRINCIPLE, IT  
14 WOULD ALL BE PATENTABLE. BUT IT'S NOT.

15 AND IN MAYO VERSUS PROMETHEUS THE COURT GAVE FURTHER  
16 ELABORATION ON WHAT AN INVENTIVE CONCEPT MEANS; THE THING THAT  
17 YOU LOOK AT BESIDES THE NATURAL PHENOMENON.

18 AND WHAT THE COURT SAID THERE IS THAT IF THE OTHER STEPS  
19 ARE WELL-UNDERSTOOD, ROUTINE AND CONVENTIONAL SCIENTIFIC  
20 ACTIVITY AT THE TIME OF THE INVENTION, THEN SIMPLY COMBINING  
21 THAT WITH A NATURAL PHENOMENON, EVEN IF IT'S NEW, DOES NOT GET  
22 YOU PATENT-ELIGIBLE SUBJECT MATTER.

23 NOW, THAT IS PRECISELY -- IT IS PRECISELY WHAT WE HAVE  
24 HERE. NO ONE IS DISPUTING THAT THE PRESENCE OF CELL-FREE FETAL  
25 NUCLEIC ACIDS IN MATERNAL SERUM OR PLASMA IS A NATURAL

1 PHENOMENON. OF COURSE IT IS.

2 OKAY. WHAT ELSE DID THE APPLICANTS BRING TO THE TABLE?  
3 DID THEY COME UP WITH A NEW AND NOVEL METHOD OF DETECTING IT?  
4 OR DID THEY RELY UPON ROUTINE, WELL-UNDERSTOOD CONVENTIONAL  
5 ACTIVITY TO DETECT IT?

6 IT IS UNDISPUTED IN THE RECORD. IT IS UNDISPUTED IN THE  
7 RECORD THAT THEY RELIED UPON ROUTINE, WELL-UNDERSTOOD  
8 CONVENTIONAL ACTIVITY.

9 HOW DO WE KNOW THAT? BECAUSE THE APPLICANTS SAID IT OVER  
10 AND OVER AGAIN IN THE PROSECUTION OF THE APPLICATION.  
11 SEQUENOM'S EXPERT SAYS IT.

12 WHAT WAS THE STATE OF THE ART AT THE TIME? THE APPLICANTS  
13 WERE NOT THE FIRST PEOPLE TO DETECT CELL-FREE DNA IN SERUM OR  
14 PLASMA. THAT HAD ALREADY BEEN DONE.

15 TUMOR CELL-FREE DNA HAD BEEN DETECTED USING THE SAME STEPS  
16 IN THAT SAME COMBINATION THAT THE APPLICANTS USED.

17 IN FACT, THE ARTICLE THAT DR. LO, ONE OF THE NAMED  
18 INVENTORS, PUBLISHED ANNOUNCING IT BEGINS BY REFERENCING THE  
19 WORK DONE WITH CELL-FREE TUMOR DNA AND SAID THAT WAS THE  
20 IMPETUS FOR HIM TO GO AND LOOK TO SEE IF THERE WAS CELL-FREE  
21 FETAL DNA.

22 SO WE HAVE A NATURAL PHENOMENON THAT IS DETECTED BY A  
23 METHOD WHICH IS INDISPUTABLY CONVENTIONAL. IT HAD ALREADY BEEN  
24 USED BY OTHERS TO DETECT CELL-FREE NUCLEIC ACIDS IN SERUM OR  
25 PLASMA.



1 THE COURT: WHEN HE WROTE THE ARTICLE ABOUT IT, DID HE SAY  
2 HOW HE FOUND IT? HE SAID:

3 "I WAS PROMPTED TO LOOK BECAUSE OF THE TUMORS, SO  
4 THEN I LOOKED FOR THE MATERNAL -- FOR THE FETAL DNA."

5 DID HE SAY HOW HE DID IT OR WHAT HE DID?

6 MR. GINDLER: YES. ALL THESE PAPERS GO THROUGH THE  
7 SCIENTIFIC PROCESS. AND IT'S ACTUALLY DESCRIBED IN THE PATENT.

8 THE COURT: AND IT'S THE SAME THING.

9 MR. GINDLER: IT'S THE SAME THING THAT'S IN THE PATENT.  
10 THE PATENT DESCRIBES THE STEPS AS BEING ROUTINE. AND THE  
11 APPLICANTS DESCRIBE THEM AS ROUTINE.

12 DR. LO IN DECLARATIONS AND IN THE PROSECUTION OF THE  
13 APPLICATION REPEATEDLY SAID THAT A SKILLED PERSON IN THE ART  
14 CAN IDENTIFY THESE FETAL NUCLEIC ACIDS USING ROUTINE,  
15 WELL-KNOWN TECHNIQUES.

16 WE CITE THIS AND REPEAT IT IN OUR OPENING PAPERS AND IN  
17 OUR OPPOSITION TO THEIR MOTION REPEATEDLY.

18 THESE ARE THE WORDS OF INVENTOR DESCRIBING HIS OWN  
19 APPLICATION, HIS OWN CLAIMS. HE IS NOT SAYING:

20 "I CAME UP WITH A UNIQUE WAY OF IDENTIFYING CELL-FREE  
21 NUCLEIC ACIDS IN SERUM OR PLASMA. HE IS SAYING:

22 "WHAT IS NEW ABOUT WHAT I DID IS I FOUND SOMETHING  
23 THAT NO ONE ELSE KNEW EXISTED BEFORE."

24 THAT'S ALL THAT HE IS SAYING. THAT IS NOT ENOUGH FOR A  
25 PATENT. BECAUSE WHAT THIS COMES DOWN TO IS: DOES IT MAKE A

1 DIFFERENCE THAT THE SOURCE OF THE CELL-FREE DNA IS FETAL AS  
2 OPPOSED TO FROM A TUMOR?

3 BECAUSE THAT IS THE ONLY DIFFERENCE, THE NATURAL  
4 PHENOMENON IS DIFFERENT. BUT BOTH TUMOR WORK AND THIS PATENT  
5 ARE USING THE SAME CONVENTIONAL STEPS TO LOOK FOR A NATURAL  
6 PHENOMENON IN SERUM OR PLASMA.

7 IT'S NOT PATENTABLE. SEQUENOM SAYS THAT IT'S ENOUGH THAT  
8 THE CLAIMS COVER THE NOVEL USE OF A NATURAL PHENOMENON. BUT  
9 THAT TEST COLLAPSES IN ON ITSELF, AND IT'S NEVER BEEN  
10 ARTICULATED AS THE TEST, BECAUSE THE ONLY THING THAT IS NEW IS  
11 THE NATURAL PHENOMENON.

12 IF THAT WAS THE TEST EVERY PATENT CLAIM THAT USES A NEWLY  
13 DISCOVERED NATURAL PHENOMENON -- JUST ASSUMING THAT IT IS NEWLY  
14 DISCOVERED IN THIS CASE -- WOULD BE PATENTABLE.

15 THAT'S NOT THE TEST. IT'S NOT HOW THE SUPREME COURT  
16 ARTICULATED THE TEST FOR OVER 40 YEARS. IT'S NEVER BEEN DONE  
17 THAT WAY.

18 AND WE HAVE QUITE A LOT MORE GUIDANCE THAN WE USED TO  
19 HAVE. WE HAVE FUNK BROTHERS. WE HAVE PARKER VERSUS FLOOK. WE  
20 HAVE MAYO VERSUS PROMETHEUS. WE HAVE MYRIAD, ALL OF WHICH ARE  
21 CONSISTENT IN SAYING WHAT YOU NEED TO DO IS TO LOOK AT THE  
22 INVENTOR'S CONTRIBUTION APART FROM THE NATURAL PHENOMENON,  
23 BECAUSE THAT'S HOW YOU PREVENT, THAT IS HOW YOU PREVENT A  
24 PATENT APPLICANT FROM CLAIMING TOO MUCH USE OF THE NATURAL  
25 PHENOMENON TO FORECLOSE FUTURE INNOVATION.

1 AND THAT'S PRECISELY WHAT IS HAPPENING HERE. EVERY  
2 PARTICIPANT IN THIS NEW MARKET IS BEING SUED FOR PATENT  
3 INFRINGEMENT. EVERYBODY.

4 WHAT DOES THAT DO? IT BLOCKS ALL INNOVATION IN THIS  
5 FIELD. THAT IS THE VICE THAT IS WARNED AGAINST BY THE SUPREME  
6 COURT'S LEGACY OF CASES HERE THAT GO UP TO MOST RECENTLY THE  
7 MYRIAD CASE.

8 SEQUENOM WAS VERY CLEAR THAT THEY SAID THAT THIS PREEMPTS  
9 THE USE OF ANY FETAL DNA. THAT'S WHY WE ARE HERE. THEY TOLD  
10 THE MARKETPLACE THAT BEFORE WE FILED OUR LAWSUIT. THAT WAS THE  
11 IMPETUS FOR OUR LAWSUIT. THEY WERE THREATENING EVERYBODY AND  
12 MAKING VERY CLEAR:

13 "YOU USE THIS NATURAL PHENOMENON, THEN YOU HAVE A  
14 PROBLEM WITH OUR PATENT."

15 THAT IS PRECISELY THE HARM WHICH IS BEING -- THAT WOULD BE  
16 ALLOWED IF THE COURT FOUND THIS TO BE PATENT-ELIGIBLE SUBJECT  
17 MATTER.

18 ONE OF THE CENTRAL ARGUMENTS THAT IS MADE BY SEQUENOM IS  
19 THAT THERE'S ESSENTIALLY A BRIGHT LINE TEST. THEY SAID IT'S  
20 VERY SIMPLE. IF THERE'S COMPLETE PREEMPTION, THEN IT IS NOT  
21 PATENT-ELIGIBLE.

22 IF IT IS NOT COMPLETE PREEMPTION, THEN IT IS  
23 PATENT-ELIGIBLE. IT'S JUST THAT SIMPLE TO SEQUENOM. BUT IT'S  
24 NOT JUST THAT SIMPLE UNDER THE CASE LAW FROM THE SUPREME COURT  
25 OR EVEN THE FEDERAL CIRCUIT.

1 THE COURT: WELL, AND THE PREEMPTION ISSUE IS IMPORTANT,  
2 BUT NOT DETERMINATIVE.

3 MR. GINDLER: CORRECT. IT IS IMPORTANT IN THE FOLLOWING  
4 SENSE. IF YOU HAVE A CLAIM WHICH DID LITERALLY PREEMPT ALL  
5 USES OF A NATURAL PHENOMENON, IT ABSOLUTELY WOULD NOT BE  
6 PATENT-ELIGIBLE BECAUSE IT WOULD NOT POSSIBLY MEET THE SUPREME  
7 COURT'S ARTICULATION OF THE STANDARD THAT THE CLAIM MUST HAVE  
8 OTHER ELEMENTS OR COMBINATION OF ELEMENTS THAT AMOUNT TO AN  
9 INVENTIVE CONCEPT THAT'S DIFFERENT THAN THE NATURAL PHENOMENON  
10 ITSELF.

11 SO IF YOU HAVE COMPLETE PREEMPTION IT COULDN'T POSSIBLY  
12 MEET THAT TEST. BUT THE KEY IS THAT THE CONVERSE IS NOT TRUE.  
13 IT IS NOT TRUE THAT IF YOU HAVE SOME USE OF A NATURAL  
14 PHENOMENON, WHICH IS NOT PREEMPTED, THAT THAT IS YOUR TICKET TO  
15 PATENT ELIGIBILITY LAND.

16 THAT'S NOT HOW THE LAW WORKS. IN FACT, IN THE RECENT CLS  
17 BANK CASE, WHICH DID NOT EVEN YIELD A MAJORITY DECISION FROM  
18 THE FEDERAL CIRCUIT, BUT THE TWO LEADING --

19 THE COURT: IS THAT THE ONE THAT HAD SEVEN DECISIONS?

20 MR. GINDLER: IT'S THE ONE THAT HAD, I THINK, AT LEAST  
21 SIX.

22 BUT IN THAT CASE, THE TWO MAJOR DECISIONS, ONE BY JUDGE  
23 LOURIE AND ONE BY JUDGE RADER, NEITHER OF THEM ADOPTS A  
24 PREEMPTION TEST.

25 JUDGE LOURIE SAID THE PROPER FOCUS IS NOT, PREEMPTION, PER

1 SEE. JUDGE RADER SAYS:

2 "EVEN IF A CLAIM DOES NOT WHOLLY PREEMPT AN ABSTRACT  
3 IDEA, IT STILL WILL NOT BE MEANINGFULLY LIMITED IF IT  
4 CONTAINS ONLY INSIGNIFICANT OR TOKEN PRE OR POST SOLUTION  
5 ACTIVITY."

6 THE COURT: JUDGE NEWMAN SAID:

7 "WITH TODAY'S JUDICIAL DEADLOCK, THE ONLY ASSURANCE  
8 IS THAT ANY SUCCESSFUL INNOVATION IS LIKELY TO BE  
9 CHALLENGED IN OPPORTUNISTIC LITIGATION WHOSE RESULT WILL  
10 DEPEND ON THE RANDOM SELECTION OF THE PANEL."

11 THAT'S WHAT SHE SAID.

12 MR. GINDLER: AND THAT IS OBVIOUSLY AN ISSUE WITH THE LACK  
13 OF GUIDANCE FROM THE FEDERAL CIRCUIT.

14 BUT HERE WE HAVE AN ADVANTAGE. AND THE ADVANTAGE IS WE  
15 HAVE AT LEAST FOUR RELEVANT UNITED STATES SUPREME COURT CASES  
16 WHICH PROVIDE VERY CLEAR GUIDANCE ON THE OUTCOME HERE.

17 THE FEDERAL CIRCUIT HAS REALLY WRESTLED WITH THE ISSUE,  
18 PARTICULARLY IN THE AREA OF ABSTRACT IDEAS AND MATHEMATICAL  
19 FORMULAS AND WHEN THEY CAN BE PATENTABLE OR IMPLEMENTED IN A  
20 COMPUTER PLATFORM, FOR EXAMPLE. HOW MUCH DOES THAT REALLY ADD  
21 TO THE ABSTRACT IDEA?

22 HERE WE'RE IN THE LIFE SCIENCES. AND WE ACTUALLY HAVE A  
23 NUMBER OF SUPREME COURT DECISIONS ACTUALLY ON THIS SUBJECT IN  
24 THE LIFE SCIENCES, STARTING WITH FUNK BROTHERS, WHICH DEALT  
25 WITH A DISCOVERY THAT A CERTAIN COMBINATION OF BACTERIA WERE

1 VERY HELPFUL TO A CERTAIN KIND OF PLANTS IN HELPING THEM ABSORB  
2 NITROGEN.

3 IT WAS A NEW DISCOVERY. AND THE COURT SAID:

4 "I'M VERY SORRY, BUT IT'S NOT PATENTABLE BECAUSE IT  
5 EXISTED IN NATURE. IT ALWAYS EXISTED IN NATURE, AND YOU  
6 FOUND IT."

7 THE COURT DIDN'T CONSIDER WHETHER OR NOT THAT PREEMPTED  
8 ALL USES OF THAT COMBINATION OF BACTERIA. SAID:

9 "SORRY, BUT THAT'S A DISCOVERY."

10 THE WAY THAT YOU KNOW IT'S NOT PREEMPTION IS ALSO TAKE A  
11 LOOK AT WHAT HAPPENED IN PARKER VERSUS FLOOK, RIGHT?

12 SO PARKER VERSUS FLOOK IS A PATENT APPLICATION WHICH  
13 COVERED A METHOD OF UPDATING ALARM LIMITS, OKAY? AND THOSE  
14 ALARM LIMITS REFLECT CERTAIN NUMERICAL MEASUREMENTS OF  
15 OPERATING CONDITIONS IN A CHAMBER.

16 SO THE ONLY THING THAT THE INVENTOR BROUGHT TO THE PATENT  
17 CLAIM WAS A MATHEMATICAL FORMULA FOR UPDATING THE ALARM LIMITS.

18 THE COURT: YES, BUT HE STUCK IT IN THE MIDDLE AND DID IT.  
19 NOBODY ELSE HAD DONE IT THAT WAY BEFORE.

20 MR. GINDLER: AND THE CLAIM WAS FOUND NOT PATENTABLE.

21 THE COURT: I KNOW.

22 MR. GINDLER: NOT PATENTABLE. NOT PATENTABLE BECAUSE THE  
23 DISCOVERY OF A PHENOMENON OF NATURE OR MATHEMATICAL FORMULA  
24 CANNOT SUPPORT A PATENT UNLESS THERE IS SOME OTHER INVENTIVE  
25 CONCEPT IN ITS APPLICATION.

1 AND THEN, THE COURT GAVE ITS MOST -- GAVE THE GUIDANCE  
2 WHICH IS QUOTED QUITE FREQUENTLY, WHICH IS THE PYTHAGOREAN  
3 FORMULA WOULD NOT HAVE BEEN PATENTABLE OR EVEN PARTIALLY  
4 PATENTABLE BECAUSE A PATENT APPLICATION CONTAINED A FINAL STEP  
5 INDICATING THAT THE FORMULA WHEN SOLVED COULD BE APPLIED TO  
6 EXISTING SURVEYING TECHNIQUES.

7 THESE CASES DON'T TALK ABOUT COMPLETE PREEMPTION. THERE'S  
8 NO COMPLETE PREEMPTION AT ALL. PARKER VERSUS FLOOK DOESN'T  
9 INVOLVE PREEMPTION OF THE USE OF THIS FORMULA. IT SAID:

10 "THE ONLY THING YOU BROUGHT TO THE TABLE WAS THIS  
11 MATHEMATICAL FORMULA. EVERYTHING THAT CAME BEFORE YOU WAS  
12 WELL-KNOWN. YOU DON'T HAVE AN INVENTIVE CONCEPT."

13 AND THAT IS THE FOCUS OF THE INQUIRY. DID THE INVENTORS  
14 OF THE '540 PATENT BRING SOMETHING TO THE TABLE IN ADDITION TO  
15 THE DISCOVERY OF A NATURAL PHENOMENON?

16 THAT'S THEIR CLAIM: THE DISCOVERY OF NATURAL PHENOMENON.  
17 AND THE ANSWER IS THEY DIDN'T.

18 MYRIAD DOES NOT CHANGE THE OUTCOME OF THIS. SO REMEMBER  
19 MYRIAD DEALS WITH THE FOLLOWING QUESTION: IS THE NATURALLY  
20 OCCURRING GENETIC SEQUENCE OF THE BRCA1 AND BRCA2 GENES  
21 PATENTABLE? AND IS A CDNA CONSTRUCT MADE IN A LAB PATENTABLE?

22 AND THE ANSWER WAS "NO," ON THE FIRST QUESTION, AND "YES,"  
23 ON THE SECOND QUESTION. "YES" ON THE SECOND QUESTION BECAUSE  
24 CDNA DOES NOT EXIST IN NATURE. YOU ARE NOT PATENTING A NATURAL  
25 PHENOMENON.

1 THE CDNA TAKES OUT THE NONCODING REGIONS. ALL THE INTRONS  
2 ARE GONE.

3 THAT WAS THE BASIS ON WHICH THE COURT MADE THE DECISION  
4 THAT CDNA, WHICH IS NOT FOUND IN NATURE, IT HAS NO COROLLARY IN  
5 NATURE, IS PATENTABLE, BUT THAT THE GENE IS NOT PATENTABLE.

6 SO LET'S ASK THE NEXT QUESTION: IF THE DISCOVERY OF THE  
7 LOCATION AND SEQUENCE OF THE BRCA GENE IS NOT PATENTABLE --

8 THE COURT: WELL, IF THEY HAD SAID:

9 "THIS IS A METHOD FOR MAKING A LOT OF THESE BRCA  
10 GENES SO" --

11 MR. GINDLER: IF THEY TRIED TO CLAIM -- IT'S A GOOD  
12 QUESTION. SO LET'S TAKE A LOOK AT WHAT THE SUPREME COURT SAID  
13 ABOUT METHOD CLAIMS, OKAY?

14 WHAT THE SUPREME COURT SAID IN MYRIAD, SAYS:

15 "IT IS IMPORTANT TO NOTE WHAT IS NOT IMPLICATED BY  
16 THIS DECISION. FIRST, THERE ARE NO METHOD CLAIMS BEFORE  
17 THIS COURT. HAD MYRIAD CREATED AN INNOVATIVE METHOD OF  
18 MANIPULATING GENES WHILE SEARCHING FOR THE BRCA1 AND BRCA2  
19 GENES, IT COULD POSSIBLY HAVE SOUGHT A METHOD PATENT."

20 BUT HERE'S THE INTERESTING LANGUAGE:

21 "BUT THE PROCESSES USED BY MYRIAD TO ISOLATE DNA,"  
22 QUOTE, 'WERE WELL UNDERSTOOD, WIDELY USED AND FAIRLY  
23 UNIFORM INsofar AS ANY SCIENTIST ENGAGED IN THE SEARCH FOR  
24 A GENE WOULD LIKELY HAVE UTILIZED A SIMILAR APPROACH.'"

25 WHAT DOES THAT TELL US ABOUT WHAT THE SUPREME COURT WOULD



1 DO WITH A CLAIM TO ISOLATE THE BRCA1 AND BRCA2 GENES THAT  
2 RELIED UPON A METHOD THAT WAS:

3 "WELL UNDERSTOOD, WIDELY USED AND FAIRLY UNIFORM  
4 INsofar AS ANY SCIENTIST ENGAGED IN THE SEARCH FOR A GENE  
5 WOULD LIKELY HAVE UTILIZED A SIMILAR APPROACH"?

6 I THINK THE ANSWER IS IT'S NOT PATENTABLE BECAUSE THAT'S  
7 WHAT THE COURT SAID IN MAYO VERSUS PROMETHEUS.

8 THE USE OF THIS LANGUAGE ISN'T A COINCIDENCE. THIS  
9 LANGUAGE COMPLETELY MIRRORS THE LANGUAGE OF ROUTINE,  
10 WELL-UNDERSTOOD, CONVENTIONAL ACTIVITY ENGAGED IN BY THE  
11 SCIENTIFIC COMMUNITY AT THE TIME TO FIND SOMETHING THAT HAD  
12 NEVER BEEN ISOLATED BEFORE, ACCORDING TO THE INVENTORS.

13 THIS LANGUAGE IS HERE FOR A REASON. THE COURT IS MAKING  
14 CLEAR THAT IT DOESN'T GET ANY BETTER IF YOU USE A  
15 WELL-UNDERSTOOD, ROUTINE METHOD TO DISCOVER THE LOCATION AND  
16 SEQUENCE OF A GENE.

17 THE COURT: HOW ABOUT IF YOU ARE LOOKING IN A PLACE NOBODY  
18 EVER LOOKED BEFORE?

19 MR. GINDLER: IF YOU ARE USING CONVENTIONAL TECHNIQUES, IT  
20 DOESN'T MAKE A DIFFERENCE. BUT KEEP IN MIND HERE THEY WEREN'T  
21 EVEN LOOKING AT SOMETHING DIFFERENT. THEY ARE LOOKING AT SERUM  
22 AND PLASMA, WHICH IS THE EXACT PLACE PEOPLE LOOKED PREVIOUSLY  
23 FOR CELL-FREE DNA.

24 WHY? BECAUSE YOU TAKE ALL THE CELLS OUT OF SERUM OR  
25 PLASMA. IT'S THE PERFECT PLACE TO LOOK FOR CELL-FREE DNA

1 BECAUSE THERE AREN'T ANY CELLS.

2 THEN, IF YOU ARE GOING TO LOOK FOR CELL-FREE DNA, YOU  
3 KNOW, LOOK FOR THE PLACE WHERE THERE ARE NO CELLS. AND IF YOU  
4 FIND IT, OKAY.

5 SO THEY LOOKED. THEY FOUND IT. THEY LOOKED IN A PLACE  
6 WHERE OTHER PEOPLE HAVE LOOKED. THEY LOOKED IN THAT PLACE  
7 BECAUSE OTHER PEOPLE HAD LOOKED THERE, AND THEY USED THE SAME  
8 METHODS THAT THE OTHERS HAD USED.

9 THIS IS NOT A CONTROVERSIAL POINT. IF YOU LOOK AT OUR  
10 PAPERS WE REPEATEDLY QUOTE THE WORDS OF THE INVENTORS  
11 THEMSELVES IN DESCRIBING THEIR METHODOLOGY AS "ROUTINE" AND AS  
12 "CONVENTIONAL." AND THAT ANYONE SKILLED IN THE ART WOULD KNOW  
13 HOW TO DETECT FETAL SEQUENCES USING THESE CONVENTIONAL AND  
14 ROUTINE METHODS.

15 THAT IS WHAT THEY RELIED UPON. AND UNDER NEARLY FOUR  
16 DECADES OF SUPREME COURT AUTHORITY IT'S NOT ENOUGH BECAUSE IT  
17 DOESN'T GET YOU TO THE INVENTIVE CONCEPT THAT MUST BE PRESENT.

18 IT'S NOT MY WORDS "INVENTIVE CONCEPT." IT'S THE SUPREME  
19 COURT'S WORDS IN PARKER VERSUS FLOOK, THE SUPREME COURT'S WORDS  
20 IN MAYO VERSUS PROMETHEUS.

21 AND THE SUPREME COURT GAVE EVEN BETTER DEFINITION TO THOSE  
22 WORDS "INVENTIVE CONCEPT" IN MAYO VERSUS PROMETHEUS IN DEALING  
23 WITH METHOD CLAIMS IN THE LIFE SCIENCES.

24 IT'S NOT GOOD ENOUGH. IT DOESN'T GET YOU PATENT  
25 ELIGIBILITY IF ALL THAT YOU DO IS USE ROUTINE, WELL-KNOWN

1 CONVENTIONAL TECHNIQUES IN CONNECTION WITH A NATURAL  
2 PHENOMENON.

3 IT'S NOT PATENTABLE.

4 THE COURT: ALL RIGHT. THANK YOU.

5 MR. GINDLER: THANK YOU.

6 THE COURT: MR. MALECEK, SO WHAT IS THE INVENTIVE CONCEPT?

7 MR. MALECEK: YOUR HONOR, THE INVENTIVE CONCEPT WAS TO  
8 TAKE A KNOWN METHOD AND TO LOOK AT IN A PLACE WHERE PEOPLE  
9 WERE -- WHERE THE FEDERAL CIRCUIT AND ALL THE EXPERTS AGREE  
10 WERE THROWING WASTE AWAY TO LOOK THERE --

11 THE COURT: OKAY. THEY WERE THROWING IT AWAY.

12 MR. MALECEK: RIGHT.

13 THE COURT: AND THEY LOOKED THERE, AND THEY FOUND THIS.

14 MR. MALECEK: AND THEY SOLVED THE BACKGROUND PROBLEM BY  
15 LOOKING SPECIFICALLY FOR PATERNALLY INHERITED NUCLEIC ACID AND  
16 BY USING AMPLIFICATION.

17 THE COURT: BUT START AGAIN. SO BEFORE THEY EVER GOT THE  
18 PATENT, WHEN THEY WROTE THE ARTICLE THEY SAID:

19 "WE LOOKED IN THE SERUM, AND WE FOUND CELL-FREE DNA  
20 FETAL," RIGHT?

21 MR. MALECEK: SO I WANT TO BE CLEAR ABOUT THE FACTUAL  
22 SITUATION. THEY DID THE EXPERIMENTS IN THE FALL -- THE FIRST  
23 EXPERIMENTS IN THE FALL OF 1996 AND CONTINUED TO DO THOSE  
24 EXPERIMENTS. THOSE SAME EXPERIMENTS ARE BOTH REPORTED IN THE  
25 "LANCET" ARTICLE AND IN THE PATENT. THERE IS TREMENDOUS

1 OVERLAP WITH THE PAPER AND THE PATENT.

2 THE COURT: OKAY.

3 MR. MALECEK: THEY ARE BOTH CONTEMPORANEOUS. THE  
4 SCIENTIFIC WORK, THE WRITING OF THE PATENT. THE FACT IT  
5 DOESN'T GET ISSUED UNTIL 2001 IS JUST THE TIME IN THE PATENT  
6 OFFICE. BUT THE PATENT IS WRITTEN IN THAT TIME FRAME.

7 THE COURT: SO THEY DO THE WORK, AND THEY FIND THEM.

8 MR. MALECEK: CORRECT.

9 THE COURT: AND THAT'S A DISCOVERY THAT'S IMPORTANT. AND  
10 THEN, THE PATENT SAYS IT'S A METHOD OF --

11 MR. MALECEK: AMPLIFYING AND DETECTING PATERNALLY  
12 INHERITED --

13 THE COURT: -- AMPLIFYING AND DETECTING PATERNALLY  
14 INHERITED --

15 MR. MALECEK: NUCLEIC ACIDS.

16 THE COURT: -- NUCLEIC ACIDS.

17 MR. MALECEK: CORRECT. AND --

18 THE COURT: AND HOW DID THEY AMPLIFY THEM.

19 MR. MALECEK: THEY AMPLIFIED THEM -- MOST OF THEIR  
20 EXPERIMENTS USED PCR.

21 THE COURT: WHICH EVERYBODY KNEW ABOUT THAT.

22 MR. MALECEK: EVERYBODY UNDERSTOOD HOW TO USE PCR.

23 THE COURT: HOW DO THEY DETECT THEM?

24 MR. MALECEK: IN MOST OF THEIR EXPERIMENTS THEY ALSO USED  
25 A LABEL, A FLUORESCENT LABEL WHICH --

1 THE COURT: WHICH PEOPLE --

2 MR. MALECEK: -- PRESENCE DURING THE PRC REACTION.

3 THE COURT: A WELL-UNDERSTOOD WAY TO DO IT, RIGHT?

4 MR. MALECEK: THAT IS CORRECT.

5 THE COURT: SO WHAT IS THE INVENTIVE CONCEPT HERE?

6 MR. MALECEK: SO, FIRST OF ALL, I WOULDN'T AGREE THAT -- I  
7 KNOW THAT'S A WORD THAT JUDGE LOURIE USED IN HIS OPINION,  
8 "INVENTIVE CONCEPT."

9 I DON'T AGREE THAT THAT'S THE STANDARD. BUT THE INVENTIVE  
10 CONCEPT WAS THE COMBINATION OF THESE INSIGHTS TO LOOK IN THAT  
11 PLACE, TO USE AMPLIFICATION, TO LOOK SPECIFICALLY FOR THE  
12 PATERNALLY INHERITED NUCLEIC ACIDS THAT ARE DIFFERENT FROM THE  
13 MOTHER'S, OKAY?

14 THE CASE LAW IS CLEAR. WHAT ARIOSAS WOULD DO, AND WHAT I  
15 WOULD DO IF I WERE IN THEIR SHOES, IS YOU WOULD CREATE A  
16 CHECKLIST, A WORD DOCUMENT WITH A TABLE. AND YOU WOULD PUT THE  
17 DIFFERENT ELEMENTS INTO THE TABLE. AND YOU WOULD SAY EITHER  
18 "CONVENTIONAL," CHECK, OR "NATURAL PHENOMENON," CHECK. OKAY?

19 AND I DON'T DISAGREE THAT IF YOU GO THROUGH ALL THE  
20 ELEMENTS IN THE CLAIM YOU COULD PUT A CHECK AS EITHER A  
21 CONVENTIONAL ITEM OR A NATURAL PHENOMENON.

22 WE DON'T DISAGREE WITH THAT, OKAY? WE'RE NOT RUNNING AWAY  
23 FROM THOSE STATEMENTS.

24 THE LAW IS CLEAR THAT WHILE YOU DO GO THROUGH THAT  
25 EXERCISE TO UNDERSTAND WHAT HAS HAPPENED, YOU HAVE TO PUT IT

1 ALL BACK TOGETHER AGAIN.

2 THIS IS WHAT THE SUPREME COURT SAID VERY RECENTLY IN MAYO  
3 ABOUT THAT. EXCUSE ME.

4 THIS IS AT 22 -- 1298. THEY GO THROUGH THESE STEPS AND  
5 THEY GET TO THE BOTTOM ONE, AND THEY SAY:

6 "FOURTH: WE HAVE TO CONSIDER THESE STEPS AS AN ORDER  
7 COMBINATION."

8 IN THIS CASE, IN MAYO, IT DIDN'T ADD ANYTHING. AND WHY  
9 DIDN'T IT ADD ANYTHING?

10 LAST SENTENCE IN THAT COLUMN:

11 "ANYONE WHO WANTS TO MAKE USE OF THESE LAWS MUST  
12 FIRST ADMINISTER THE DRUG AND MEASURE THE RESULTING  
13 METABOLITE CONCENTRATIONS."

14 AND SO THE COMBINATION AMOUNTS TO NOTHING MORE THAN THE  
15 INSTRUCTIONS TO APPLY THE LAWS WHEN TREATING THEIR PATIENTS.

16 THE COURT: I'M SORRY. JUST READ THAT AGAIN, PLEASE.

17 MR. MALECEK: SO EVERYONE WHO DOES THIS HAS TO DO THE  
18 STEPS. ONLY DOCTORS ARE GIVING PEOPLE DRUGS. SO ALL THE  
19 PEOPLE THAT ARE PRACTICING THIS CLAIM ARE GOING TO GIVE THEIR  
20 PATIENT A DRUG.

21 ALL THE DOCTORS THAT ARE PRACTICING THIS CLAIM WERE  
22 ALREADY, BEFORE THIS CLAIM WAS WRITTEN, MEASURING THE LEVELS.  
23 AND ALL THE DOCTORS THAT WERE ALREADY PRACTICING THIS CLAIM  
24 WERE ALREADY ADJUSTING THEIR LEVELS BASED ON THIS.

25 THERE'S NO WAY TO ADMINISTER THESE DRUGS WITHOUT VIOLATING

1 THIS CLAIM. YOU'VE TOTALLY DOMINATED THAT NATURAL PHENOMENON.

2 THAT IS NOT TRUE IN EVERY DIMENSION OF THE '540 CLAIM.  
3 AND I WOULD AGREE WITH THE COURT THAT THIS 101 JURISPRUDENCE  
4 IS HARD AND SLIPPERY. BUT I WOULD NOT AGREE WITH THE COURT  
5 THAT THIS IS A CLOSE QUESTION.

6 IF THE COURT IS CAREFUL AND EXAMINES THE CLAIM LANGUAGE AT  
7 ISSUE IN EACH OF THESE CASES, THE PRIOR JURISPRUDENCE AND  
8 COMPARES IT TO THE '540 CLAIM. AND IF THE COURT COMPARES --  
9 FOR EXAMPLE, LET ME START WITH THE PREEMPTION POINT. LOOK AT  
10 THE DISCUSSION OF PREEMPTION AND WHAT THEY FIND IS OUTSIDE OF  
11 THE SCOPE OF THE CLAIMS.

12 IF THIS CASE GETS TO THE FEDERAL CIRCUIT AND GETS AN  
13 OPINION ON THIS ISSUE, IT WILL BE THE FIRST ONE WHERE WE HAVE  
14 THREE PEER-REVIEWED ARTICLES TAKING ADVANTAGE OF AN UNDERLYING  
15 NATURAL PHENOMENON, A CELL-FREE DNA, WITHOUT PRACTICING THE  
16 '540 PATENT ON THREE DIFFERENT REASONS.

17 ONE IS YOU CAN DO IT WITHOUT AMPLIFYING.

18 ANOTHER IS YOU CAN DO IT WITHOUT DISTINGUISHING BETWEEN  
19 THE MATERNAL AND THE PATERNAL.

20 AND THE THIRD JUST SLIPPED OUT OF MY MIND. BUT IT'S  
21 FRACTIONATION. YOU CAN DO IT ON THE WHOLE BLOOD, NOT JUST ON  
22 THE CELL (SIC) OR PLASMA. THAT IS WHAT THEIR OWN EXPERT  
23 PUBLISHED ON.

24 THIS WILL BE THE CLEAREST CASE OF ESTABLISHED FACTS  
25 SHOWING THAT THE '540 PATENT DOES NOT DOMINATE THE USE OF

1 CELL-FREE FETAL DNA EVER.

2 THE COURT: SAY AGAIN THOSE THREE THINGS THAT YOU SAY ARE  
3 DIFFERENCES.

4 MR. MALECEK: RIGHT. SO THESE ARE SUMMARIZED IN OUR REPLY  
5 BRIEF. I THINK -- AND I'LL GET THE PAGE FOR YOU IN A MINUTE.  
6 I THINK IT'S 20 SOMETHING AGAIN.

7 BUT BISCHOFF WAS THEIR EXPERT IN THIS AREA, AND SHE HAS A  
8 PEER-REVIEWED PUBLICATION WHERE SHE SAID:

9 "LOOK, I'M INTERESTED IN DR. LO'S WORK. I'VE BEEN IN  
10 THIS FIELD FOR A LONG TIME. I'M GOING TO SEE IF I CAN DO  
11 THIS IN WHOLE BLOOD."

12 AND SHE DID. SHE SUCCESSFULLY DID IT IN THE WHOLE BLOOD.

13 THE COURT: SOMEBODY DID IT IN THE WHOLE BLOOD, AND TWO  
14 OTHER WAYS, BUT NOBODY DID IT IN SERUM.

15 MR. MALECEK: NO, DR. LO DID IT IN SERUM. THE POINT IS  
16 THAT AFTER THE '540 PATENT IS OUT THE JURISPRUDENCE OF THE 101  
17 CLEARLY DIRECTS US TO LOOK AND SEE IF YOU CAN USE THE  
18 UNDERLYING NATURAL PHENOMENON WITHOUT USING THE PATENT, RIGHT?  
19 THAT'S WHAT THE PREEMPTION ANALYSIS IS.

20 AND IT IS A CLEAR DIRECTION FROM THE SUPREME COURT AND THE  
21 FEDERAL CIRCUIT THAT WE SHOULD ENGAGE IN THAT PREEMPTION  
22 ANALYSIS.

23 THE COURT: WELL, I GUESS ONE OF THE ISSUES ON THAT -- AND  
24 I ACTUALLY DON'T THINK THAT IS THE DISPOSITIVE ISSUE HERE. BUT  
25 LET'S SAY WE'RE TALKING ABOUT THAT, AND YOUR PATENT SAYS IT'S A



1 WAY TO IDENTIFY MATERNALLY INHERITED CELL-FREE --

2 MR. MALECEK: DNA.

3 THE COURT: -- FETAL DNA IN THE MOTHER'S SERUM. AND THE  
4 METHOD IS YOU AMPLIFY THE SERUM AND YOU FIND IT.

5 MR. MALECEK: UNDERSTOOD, JUDGE. SO WHAT IS THE NATURAL  
6 PHENOMENON?

7 THE COURT: AND YOU CAN AMPLIFY IT PRESUMABLY ANY WAY YOU  
8 WANT. AND YOU CAN FIND IT ANY WAY YOU WANT. SO IF YOU ARE  
9 GOING TO BE LOOKING FOR THE CELL-FREE DNA IN THE MOTHER'S  
10 SERUM, WHICH YOU ARE NOW THAT THEY FIGURED OUT IT'S THERE,  
11 PRETTY MUCH ANYTHING YOU DO IS GOING TO BE --

12 MR. MALECEK: NO. THAT IS WHERE THE COURT IS WRONG, WRONG  
13 AS THE DAY IS LONG. YOU CAN -- THERE'S -- THE NATURAL  
14 PHENOMENON IS THE CELL-FREE FETAL DNA.

15 THE COURT: RIGHT.

16 MR. MALECEK: IT'S THERE. YOU CAN FIND IT WITHOUT  
17 AMPLIFYING, PERIOD. PEER-REVIEWED LITERATURE --

18 THE COURT: WOULDN'T ANY LOGICAL PERSON AMPLIFY IT FIRST  
19 SO THERE WILL BE MORE TO FIND?

20 MR. MALECEK: NOT NECESSARILY. THESE PEOPLE HAVE -- I'M  
21 NOT MAKING THIS UP, JUDGE. THIS IS PEER-REVIEWED SCIENTIFIC  
22 LITERATURE ON A NEXT-GEN SEQUENCING MACHINE PUT OUT BY A  
23 COMPANY CALLED "HELICOS," OKAY?

24 NOW, THEY MAKE FUN OF THAT BECAUSE HELICOS WENT OUT OF  
25 BUSINESS BECAUSE THEIR MACHINE WAS REALLY EXPENSIVE.

1 THE COURT: AND THEY DIDN'T GET ENOUGH, SO THEY HAD TO  
2 AMPLIFY BEFORE THEY COUNTED IT, RIGHT?

3 MR. MALECEK: MACHINE WORKS. THEY TESTED REAL FETAL  
4 SAMPLES. THE ARTICLES ARE IN THE RECORD, JUDGE. THEY DID THIS  
5 WITHOUT AMPLIFICATION. WHICH, BY THE WAY, OFFERS -- THAT  
6 INNOVATION OF DOING IT WITHOUT AMPLIFICATION OFFERS SCIENTIFIC  
7 BENEFITS, BECAUSE THE AMPLIFICATION STEPS CAN GIVE YOU WRONG  
8 ANSWERS, RIGHT?

9 AND SO DOING IT WITHOUT AMPLIFICATION IS MORE PRECISE.  
10 AND YOU CAN READ THE LITERATURE. AND RIGHT IN THERE THEY  
11 DESCRIBE THAT THIS IS AN ADVANTAGE, AND INNOVATION OUTSIDE OF  
12 THE '540 USING THE UNDERLYING NATURAL PHENOMENON WITHOUT  
13 AMPLIFICATION.

14 OKAY? PEER-REVIEWED SCIENTIFIC LITERATURE. NOT A  
15 SINGLE -- THERE'S CASES THROUGHOUT THE 101, SOME ON ONE SIDE,  
16 SOME ON THE OTHER. NOT ONE OF THEM HAS POINTED TO  
17 PEER-REVIEWED LITERATURE AS SAYING:

18 "THIS IS WHAT SHOWS THERE IS NO PREEMPTION."

19 IT'S:

20 "WELL, IT COULD HAVE BEEN DONE THIS WAY."

21 IT'S SPECULATION, SO ON AND SO FORTH.

22 THAT'S ONE EXAMPLE OF PEER-REVIEWED LITERATURE.

23 SECOND EXAMPLE OF PEER-REVIEWED LITERATURE: THEIR EXPERT,  
24 THE EXPERT THEY CHOSE, BISCHOFF, DID THIS IN WHOLE BLOOD. THE  
25 ARTICLE IS PART OF THE RECORD BEFORE THIS COURT.

1 SO YOU DO NOT HAVE TO FRACTIONATE THE BLOOD. YOU CAN USE  
2 THE WHOLE BLOOD IF YOU WANT, OKAY?

3 AGAIN, THAT IS OUTSIDE OF THE '540. THAT IS USING THE  
4 CELL-FREE DNA WITHOUT PRACTICING THE '540 PATENT, OKAY?

5 EXAMPLE NUMBER TWO: PEER-REVIEWED.

6 EXAMPLE NUMBER THREE: DR. LO'S LAB. YOU'VE HEARD -- THE  
7 COURT'S HEARD A COUPLE DIFFERENT TIMES ABOUT THE METHYLATION  
8 DIFFERENCES THAT ARE NOT INHERITED FROM THE MOTHER OR THE  
9 FATHER.

10 AND THEY HAVE BEEN ABLE TO DEMONSTRATE THAT YOU CAN USE  
11 THOSE DIFFERENCES TO DISTINGUISH THE FETAL DNA. NOT BECAUSE  
12 YOU KNOW IT'S FROM MOM OR DAD, BUT BECAUSE YOU CAN SEE THAT THE  
13 FETAL DNA IS METHYLATED DIFFERENTLY.

14 AGAIN, SCIENTIFIC PUBLICATION, PEER-REVIEWED, REAL  
15 SAMPLES, REAL RESULTS, USING THE UNDERLYING NATURAL PHENOMENON  
16 OF CELL-FREE DNA WITHOUT USING THE '540.

17 THIS IS NOT A CLOSE CASE WHEN YOU HAVE THREE CONCRETE  
18 EXAMPLES ABOUT THREE DIFFERENT AXES IN THE PATENT, THREE  
19 DIFFERENT ELEMENTS OF THE PATENT THAT ARE REQUIRED TO PRACTICE  
20 IT THAT YOU DON'T PRACTICE.

21 IT'S AS CLEAR AS THE DAY IS LONG THAT THAT PREEMPTION  
22 ANALYSIS MAKES THIS PATENT NOT DOMINATE THE AREA. AND THE  
23 JURISPRUDENCE IS ALSO CLEAR THAT THE CHECK BOXES IS NOT THE  
24 END. YOU HAVE TO PUT THINGS BACK TOGETHER AND DO THE  
25 PREEMPTION ANALYSIS. OKAY?

1 AND JUDGE LOURIE AND JUDGE RADER BOTH AGREED WITH THAT,  
2 ALL RIGHT? THAT THE PREEMPTION ANALYSIS MUST BE DONE. IT'S  
3 NOT SIMPLY DISSECTING THE CLAIM. AND THE LAW IS VERY CLEAR  
4 ABOUT THAT.

5 I WANT TO MAKE --

6 THE COURT: THE LAW IS VERY CLEAR ABOUT THAT?

7 MR. MALECEK: IT IS.

8 THE COURT: TWO OUT OF THE SEVEN SAID THAT.

9 MR. MALECEK: OF THE OPINIONS IN FRONT OF CLS?

10 THE COURT: YES.

11 MR. MALECEK: I THINK THEY ALL AGREE THAT PREEMPTION  
12 ANALYSIS SHOULD BE DONE. RADER ACTUALLY --

13 THE COURT: YOU SAY IT --

14 MR. MALECEK: YES. I THINK JUDGE RADER ACTUALLY WOULD --  
15 HE HAS THAT FUNNY LAST -- DO WE COUNT IT AS AN OPINION, HIS  
16 NOTE, HIS PERSONAL REFLECTION?

17 AND THERE HE SAYS:

18 "I WISH WE WOULDN'T HAVE TO DO THIS PREEMPTION STUFF  
19 BECAUSE I THINK WE'VE GONE TOO FAR DOWN THIS PATH."

20 AND ONE OF THE OTHER POINTS I WANT TO MAKE SURE TO MAKE  
21 TODAY IS THE POINT THAT HE MAKES IN THAT REFLECTION, WHICH IS:

22 "CAN'T WE JUST START WITH THE STATUTE," RIGHT?

23 SO THERE'S NO DISPUTE -- I THINK WE WANT TO BE CLEAR ABOUT  
24 THAT -- THAT THIS IS -- THAT THE STATUTE 101 THAT SAYS WHAT CAN  
25 BE ELIGIBLE TO BE PATENTED, BECAUSE THAT'S WHAT WE'RE TALKING

1 ABOUT, SAYS:

2 "WHOEVER INVENTS OR DISCOVERS," OKAY?

3 "DISCOVERY" IS NOT A BAD WORD IN THE PATENT STATUTE.  
4 WE'VE TRIED TO MAKE IT INTO A BAD WORD IN THIS CASE, BUT IT'S  
5 NOT. IF YOU DISCOVER SOMETHING, THAT'S A GOOD THING IN THE  
6 PATENT STATUTE'S VIEW.

7 "ANY NEW OR USEFUL PROCESS, MACHINE, MANUFACTURE OR  
8 COMPOSITION OF MATTER OR ANY NEW AND USEFUL IMPROVEMENT  
9 THEREOF MAY OBTAIN A PATENT THEREFORE SUBJECT TO THE  
10 REMAINING PRONGS OF THE STATUTE."

11 AND IT'S CLEAR THAT THAT IS THIS OPENING ELIGIBILITY. AND  
12 JUDGE RADER IS TRYING TO REIN US ALL BACK IN AND SAY:

13 "THIS IS WHAT IS ELIGIBLE. THIS IS THE TOP OF THE  
14 PIPELINE OF THINGS THAT CAN COME INTO THE PATENTING  
15 PROCESS," OKAY?

16 SO I WANTED TO MAKE SURE THAT WE DIDN'T LOSE TRACK OF THE  
17 FACT THAT THAT'S THE STATUTE WE'RE TRYING TO UNDERSTAND.

18 SECOND OF ALL, SO THEN WE GET TO A POINT WHERE WE'RE  
19 SAYING:

20 "BUT IS IT AN EXCEPTION? IS IT AN EXCEPTION TO THE  
21 BREADTH OF THAT?"

22 THAT'S WHAT WE'RE TRYING TO FIND OUT. AND WE'RE TRYING TO  
23 FIND THAT OUT UNDER A CLEAR AND CONVINCING STANDARD THAT THEY  
24 BEAR THE PROOF OF.

25 AND, AGAIN, I WOULD -- AS I STRUGGLE TO GET MY HEAD AROUND

1 LOTS OF VERY SLIPPERY LANGUAGE, I GO BACK TO FACTS. I GO BACK  
2 TO LAW SCHOOL AND I COMPARE FACTS OF CLAIMS TO FACTS OF CLAIMS.

3 THE FUNK BROTHERS CLAIM WAS COMBINE ANY BACTERIAS THAT  
4 DON'T INTERFERE WITH EACH OTHER, PERIOD. PERIOD. THAT WAS IT.  
5 THAT WAS FOUND PATENT-INELIGIBLE.

6 AND THIS IS RIGHT IN FOOTNOTE ONE OF IT:

7 "AN INOCULANT FOR THE PLANTS COMPRISING A PLURALITY  
8 OF SELECTED MUTUALLY NON-INHIBITED STRAINS OF DIFFERENT  
9 SPECIES OF BACTERIA, SUCH STRAINS BEING UNEFFECTED BY EACH  
10 OTHER."

11 ANY STRAINS YOU PICK. I'M NOT TELLING YOU WHICH ONES.  
12 COMBINED TOGETHER AS LONG AS THEY DON'T INHIBIT EACH OTHER,  
13 WHICH I'M NOT TELLING YOU, YOU KNOW, WHICH ONES DO AND DO NOT  
14 INHIBIT EACH OTHER.

15 THAT'S THE CLAIM THAT WAS INVALIDATED, RIGHT?

16 AND THERE'S A LOT OF DISCUSSION ABOUT HOW THAT DISCOVERY  
17 COULD HAVE LED TO LOTS OF OTHER PATENTS. BUT THAT PARTICULAR  
18 CLAIM IS INVALID.

19 IT GOES BACK TO THE: HERE'S A NATURAL PHENOMENON. APPLY  
20 IT.

21 LOOK AT MYRIAD, RIGHT? THE FEDERAL CIRCUIT HAS ASKED US  
22 TO LOOK AT MYRIAD TO GET DIRECTION. THREE CLAIMS THIS COURT  
23 SHOULD HAVE IN MIND WHEN IT STUDIES MYRIAD AND IS COMPARING  
24 THIS TO THE '540.

25 THE FIRST CLAIM IS THE CLAIM THAT WAS HELD INVALID. THAT

1 CLAIM READS:

2 "AN ISOLATED DNA CODING FOR A BRCA 1 POLYPEPTIDE,  
3 SAID POLYPEPTIDE HAVING THE AMINO ACID SEQUENCES SET FORTH  
4 IN SEQUENCE I.D. NUMBER TWO." STOP.

5 THEY GOT A PATENT ON THE SEQUENCE THAT EXISTS IN OUR HUMAN  
6 GENOME, OKAY?

7 MYRIAD WAS ARGUING BECAUSE WE PULL THAT OUT, 3 BILLION  
8 BASE PAIRS, WE STOP AT THIS END AND STOP AT THIS END AND PULL  
9 IT OUT AND ISOLATE IT. THAT SHOULD BE PATENTABLE.

10 AND THE SUPREME COURT SAID:

11 "NO. JUST ISOLATING IT, YOU KNOW, ARGUABLY CHANGES  
12 IT FROM ONE MOLECULE TO ANOTHER, BUT THAT'S NOT ENOUGH.'.

13 OKAY? WE KNOW THAT. THAT HOW MUCH ABOVE THAT DO I HAVE  
14 TO GO TO GET A PATENT? RIGHT?

15 WE HAVE SOME GUIDANCE ON THAT. FACTUAL GUIDANCE IN  
16 MYRIAD. CDNA. THE NEXT CLAIM, CLAIM TWO, IS VALID. THE  
17 ISOLATED DNA OF CLAIM ONE:

18 "WHEREIN SAID DNA HAS THE NUCLEOTIDE SEQUENCE SET  
19 FORTH IN SEQUENCE I.D. NUMBER ONE," PERIOD. FULL STOP.  
20 THAT CLAIM IS VALID UNDER MYRIAD. OKAY?

21 HOW DOES CDNA GET CREATED? DESCRIBED IN MYRIAD.  
22 DESCRIBED AT 212:

23 "YOUR MESSENGER RNA NATURALLY, THROUGH NO  
24 INTERVENTION OF A SCIENTIST, TAKES OUT THE EXONS AND  
25 CODONS AND IT'S RNA RATHER THAN DNA."

1 THAT'S A NATURAL SEQUENCE THAT OCCURS IN NATURE.

2 YOU PUT IN AN ENZYME AND NUCLEOTIDES AND MAKE A COPY OF  
3 THAT, AND IT'S CDNA. PATENTABLE.

4 PAGE 2119 OF THE OPINION, FOLKS ARE ARGUING ABOUT THE MRNA  
5 IS NATURALLY OCCURRING. THEY NEVERTHELESS ARGUE THAT CDNA IS  
6 NOT PATENT-ELIGIBLE BECAUSE THE NUCLEOTIDE SEQUENCE OF THE CDNA  
7 IS DICTATED BY NATURE, NOT BY THE LAB TECHNICIAN.

8 SUPREME COURT:

9 "THAT MAY BE SO, BUT THE LAB TECHNICIAN  
10 UNQUESTIONABLY CREATES SOMETHING NEW WHEN CDNA IS MADE."

11 THAT'S WHERE THEY DREW THE LINE, JUDGE: MAKING A COPY OF  
12 A GENETIC SEQUENCE THAT EXISTS IN NATURE, CHANGING IT FROM MRNA  
13 TO CDNA IS PATENTABLE, OKAY?

14 I THINK YOU'VE GOT TO HAVE THESE FACTUAL ROADMAPS FROM  
15 MYRIAD IN MIND WHEN YOU MAKE THE DECISION.

16 SECTION THREE OF THIS OPINION -- A UNANIMOUS AND  
17 RELATIVELY SHORT OPINION. THAT'S A MIRACLE IN TODAY'S DAY AND  
18 AGE -- GIVES FURTHER GUIDANCE. THE SUPREME COURT TOOK AN EXTRA  
19 STEP. IT HAS THREE PARAGRAPHS IN SECTION THREE.

20 IT'S AT 219 TO 220. THE FIRST PARAGRAPH WAS WHAT MR.  
21 GINDLER WAS FOCUSING ON.

22 THE SECOND PARAGRAPH IS ANOTHER VERY IMPORTANT PLACE FOR  
23 THIS COURT TO TURN TO UNDERSTAND MYRIAD BECAUSE IT POINTS US TO  
24 A THIRD TYPE OF CLAIM THAT IS PATENTABLE.

25 THE COURT: WHY DON'T YOU READ THE SECOND ONE AGAIN, AND



1 THEN READ -- IF THERE ARE THREE PARAGRAPHS THERE, TELL ME WHAT  
2 THE FIRST -- I KNOW HE ABOUT IT, BUT SAY IT AGAIN, AND THEN DO  
3 THE SECOND.

4 MR. MALECEK: OKAY. I WON'T READ THEM ALL, BECAUSE THEY  
5 ARE A LITTLE LONG. BUT I'LL PUT ENOUGH IN THE RECORD SO YOU  
6 CAN GET TO THEM.

7 IT'S A THREE-PARAGRAPH SECTION. IT HAS THREE AT THE TOP  
8 OF THE HEADING. IT'S AT 219 AND 220.

9 THE FIRST ONE IS THERE ARE -- "IT'S IMPORTANT TO NOTE WHAT  
10 IS NOT IMPLICATED BY THIS DECISION." THAT'S THE OPENING OF THE  
11 SECTION.

12 "THE FIRST THERE ARE NO METHOD CLAIMS. AND HAD  
13 MYRIAD COME UP WITH SOME NEW METHOD FOR FINDING THE BRCA  
14 GENES THAT WOULD BE PATENTABLE," IS THE NEGATIVE  
15 IMPLICATION, ALL RIGHT? BUT THEY DIDN'T. THEY USED  
16 CONVENTIONAL MEANS.

17 THE COURT: OKAY? HAD THEY COME UP WITH A NEW METHOD,  
18 WHICH THEY DID NOT.

19 MR. MALECEK: RIGHT. AND THAT'S WHAT MR. GINDLER WAS  
20 REFERRING TO.

21 THE SECOND PARAGRAPH SAYS:

22 "SIMILARLY, THIS CASE DOES NOT INVOLVE PATENTS  
23 ON NEW APPLICATIONS," ITALICIZED, THEIR ITALICS, "OF  
24 KNOWLEDGE ABOUT THE BRCA AND BRCA2 GENES," JUDGE BRYSON  
25 APTLY NOTED.

1 SO THEY ARE APPROVINGLY REACHING OUT TO A REMARK THAT  
2 JUDGE BRYSON MADE BELOW IN THE DISSENT.

3 "AS THE FIRST PARTY WITH KNOWLEDGE OF THE BRCA1 AND  
4 BRCA2 SEQUENCES" -- THE DISCOVERER, RIGHT? -- MYRIAD WAS  
5 IN AN EXCELLENT POSITION TO CLAIM APPLICATIONS OF THAT  
6 KNOWLEDGE. MANY OF ITS UNCHALLENGED CLAIMS ARE LIMITED TO  
7 SUCH APPLICATIONS."

8 CITING TO 689 F.3D AT 1349.

9 IF THE COURT WERE TO GO TO 689 F.3D AT 1349, THERE IS A  
10 CITATION IN BRYSON'S OPINION IMMEDIATELY AFTER THAT TO THE  
11 CLAIMS THAT HE HAS IN MIND. THAT INCLUDES CLAIM 21 OF THE '441  
12 PATENT, WHICH WE HAVE REPRODUCED IN ITS ENTIRETY AT PAGE 12 OF  
13 OUR OPPOSITION BRIEF.

14 HAVING DISCOVERED BRCA1 AND BRCA2 GENES, BRYSON AND THE  
15 SUPREME COURT SAID:

16 "YOU MIGHT BE ELIGIBLE FOR AN APPLICATION OF THAT  
17 KNOWLEDGE THAT READS LIKE THIS: THE METHOD OF CLAIM 20  
18 WHEREIN A GERMLINE ALTERATION" -- A MUTATION -- "IS  
19 DETECTED BY HYBRIDIZING A BRCA1 GENE PROBE WHICH  
20 SPECIFICALLY HYBRIDIZES TO AN ALLELE OF ONE OF SAID  
21 ALTERATIONS TO RNA ISOLATED FROM SAID HUMAN SAMPLE AND  
22 DETECTING THE PRESENCE OF A HYBRIDIZATION PRODUCT WHEREIN  
23 THE PRESENCE OF SAID PRODUCT INDICATES THE PRESENCE OF  
24 SAID ALLELE IN THE SAMPLE."

25 FOR 20 PLUS YEARS BEFORE THERE WAS PCR, YOU COULD DO

1 HYBRIDIZATION OF A PROBE TO SEE IF A SEQUENCE WAS PRESENT IN A  
2 GENE. THAT IS WHAT THEY CLAIMED HERE. HYBRIDIZE A PROBE, A  
3 WELL-KNOWN CONVENTIONAL ACTIVITY FOR DETERMINING WHETHER A  
4 PARTICULAR MUTATION OF THE BRCA1 OR BRCA2 GENE ARE PRESENT.

5 AND THAT IS WHAT JUDGE BRYSON TOOK THE TIME TO CALL OUT AS  
6 THE KIND OF THING A DISCOVERER WOULD BE ABLE TO PATENT.

7 AND THE SUPREME COURT MADE THE EFFORT TO INCLUDE IN ITS  
8 OPINION, ADMITTEDLY DICTA, TO GIVE GUIDANCE TO COURTS LIKE  
9 THIS: THAT'S THE KIND OF CLAIM WE SHOULD EXPECT A DISCOVERER  
10 TO HAVE. PURELY CONVENTIONAL ACTIVITY, HYBRIDIZATION PROBES,  
11 TO DETECT A SEQUENCE THAT THEY HAD DISCOVERED, OKAY?

12 THREE CLAIMS ARE PRESENT IN THIS MYRIAD DECISION FOR THE  
13 COURT TO COMPARE THE SCOPE OF TO THE SCOPE OF THE '540.

14 IT'S A WAY TO GET OUT OF THE TRAP OF TRYING TO UNDERSTAND  
15 WHAT THESE VAGUE WORDS MEAN AND MAKE A REAL COMMON LAW, LAW  
16 SCHOOL FACTUAL COMPARISON OF: WHAT IS THE CLAIM?

17 PREEMPTION SERVES A SIMILAR PURPOSE BECAUSE, YOU KNOW, THE  
18 COURTS THEMSELVES ARE OBVIOUSLY STRUGGLING WITH HOW TO DO THIS.  
19 AND THE WORDS THEMSELVES DON'T REALLY PROVIDE GUIDANCE.

20 IT'S GOT TO BE A FACTUAL ANALYSIS. AND THERE IS NOT A  
21 SINGLE CASE YET WHERE THE 101 ANALYSIS HAS BEEN SHOWN NOT TO  
22 PREEMPT THE ATTACKED CLAIM NOT --

23 THE COURT: LET'S SAY --

24 MR. MALECEK: -- TO PREEMPT WITH THREE DIFFERENT ARTICLES.

25 THE COURT: -- I WANT TO WRITE AN OPINION IN YOUR FAVOR.

1 MR. MALECEK: YES.

2 THE COURT: AND I WANT TO START OUT BY SAYING:

3 "WELL, EVERYBODY, THEY HAD THE INVENTORS HERE HAD  
4 GIVEN TO THE WORLD THE SCIENTIFIC UNDERSTANDING THAT  
5 THERE'S FETAL DNA FRAGMENTS IN THE MOM'S PLASMA."

6 MR. MALECEK: ABSOLUTELY.

7 THE COURT: BUT IN ADDITION THIS PATENT DOES WHAT? WHAT  
8 DO I SAY?

9 MR. MALECEK: IT REQUIRES AMPLIFICATION WHICH IS NOT  
10 NECESSARY TO USE THAT NATURAL PHENOMENON. IT REQUIRES THE USE  
11 OF A PLASMA AND SERUM SAMPLE, WHICH IS NOT NECESSARY TO USE THE  
12 UNDERLYING NATURAL PHENOMENON.

13 IT REQUIRES THE DETECTION OF PATERNALLY INHERITED NUCLEIC  
14 ACIDS WHICH ARE DIFFERENT FROM THE MOTHERS' WHICH IS NOT  
15 REQUIRED TO USE THE UNDERLYING NATURAL PHENOMENON.

16 "AND WHEN I SAY" -- SPEAKING FOR YOU NOW -- "WHEN I SAY IT  
17 DOESN'T REQUIRE THE USE OF THESE THINGS, I'M NOT MAKING  
18 THIS UP. IT'S BASED ON PEER-REVIEWED SCIENTIFIC  
19 PUBLICATIONS USING REAL SAMPLES FROM REAL PREGNANT WOMEN,  
20 AND IT WORKED. AND IF THAT DOESN'T SHOW -- IF I'M HERE  
21 STRUGGLING AS A DISTRICT COURT JUDGE, AND I'M BEING TOLD  
22 TO USE PREEMPTION AS A TOOL TO UNDERSTAND THIS, HOW CAN  
23 I -- THIS IS THREE DIFFERENT WAYS THAT YOU CAN USE THE  
24 UNDERLYING PHENOMENON AND BE OUTSIDE OF THREE INDEPENDENT  
25 CLAIM LIMITATIONS."

1 INDEPENDENT CLAIM LIMITATIONS. THIS GOES FARTHER THAN ANY  
2 OTHER 101 CASE TO DATE IN DEMONSTRATING A LACK OF PREEMPTION.

3 THE COURT: OKAY. SO WHAT I'M TO SAY IS THE NEW IDEA HERE  
4 IS, WELL, THERE WOULD BE OTHER WAYS TO DO IT, SO IT'S NOT  
5 PREEMPTED. SO THE NEW IDEA IS THIS IS A COMPLETELY TRADITIONAL  
6 WAY TO DO IT, BUT IT DOESN'T PREEMPT OTHER WAYS TO DO IT. IS  
7 THAT THE NEW IDEA?

8 MR. MALECEK: THAT'S EXACTLY RIGHT, YOUR HONOR.

9 THE COURT: WELL, THAT DOESN'T SOUND LIKE MUCH OF A NEW  
10 IDEA. A COMPLETELY TRADITIONAL WAY TO DO IT, BUT THERE MIGHT  
11 BE OTHER WAYS. SO MY NEW IDEA IS A COMPLETELY TRADITIONAL WAY  
12 TO DO IT.

13 MR. MALECEK: YOUR HONOR, I THINK THAT YOU ARE FALLING  
14 INTO THE TRAP THAT THE CASES TRY AND STEER US AWAY FROM.

15 THEY SAY I GO THROUGH THINGS, AND I CHECK IF IT'S  
16 CONVENTIONAL. I CHECK IF IT'S A PHENOMENON OR AN ABSTRACT  
17 IDEA, WHATEVER, RIGHT.

18 THE COURT: I'M JUST TRYING TO ISOLATE THE NEW IDEA THAT  
19 IS HERE.

20 MR. MALECEK: RIGHT. THE NEW IDEA WAS TO USE THOSE  
21 CONVENTIONAL TECHNIQUES TO DETECT A SPECIFIC THING IN A  
22 SPECIFIC WAY THAT HAD NEVER BEEN DONE BEFORE AND CHANGE THE WAY  
23 THAT PRENATAL DIAGNOSIS WAS DONE.

24 I MEAN, THERE'S 1700 CITATIONS TO THAT "LANCET" ARTICLE,  
25 JUDGE. ALL THE EXPERTS, INCLUDING PEOPLE WHO ARE ON THE

1 SCIENTIFIC ADVISORY BOARDS OF THESE COMPANIES, WE PUT THIS IN  
2 THE RECORD IN THE PI AND ELSEWHERE, SAID IT CHANGED THE NATURE  
3 OF PRENATAL AND NONINVASIVE DIAGNOSIS.

4 THE COURT: "IT." WHAT WAS "IT? "IT" WAS THE DISCOVERY  
5 OF THE CELL-FREE FETAL DNA IN THE SERUM.

6 MR. MALECEK: CORRECT.

7 THE COURT: THAT IS WHAT CHANGED EVERYTHING.

8 MR. MALECEK: CORRECT. AND THE PATENT STATUTE THAT WE'RE  
9 TALKING ABOUT, SECTION 101 SAYS:

10 "ANY" -- I HAVE TO READ IT CORRECTLY, NOT JUST MAKE  
11 IT UP, RIGHT?

12 "WHOEVER INVENTS OR DISCOVERS ANY NEW OR USEFUL  
13 PROCESS, MACHINE, MANUFACTURE, COMPOSITION OF MATTER OR  
14 NEW AND USEFUL IMPROVEMENTS THEREOF MAY OBTAIN A PATENT."

15 WE HAVE DENIGRATED THE IDEA THAT THERE'S A DISCOVERY HERE  
16 AND, THEREFORE, YOU CAN'T USE CONVENTIONAL TECHNIQUES AND  
17 COMBINE THEM WITH THE DISCOVERY AND HAVE AN INVENTION.

18 THAT'S JUST NOT WHERE THE LAW IS. IF YOU MAKE A NEW  
19 DISCOVERY AND CAN -- YOU'RE EINSTEIN. YOU DISCOVER E EQUALS MC  
20 SQUARED, AND YOU GO OUT AND USE THINGS THAT ARE IN THE WORLD TO  
21 APPLY THAT TO MAKE A MACHINE THAT DOES SOMETHING THAT'S  
22 DEPENDENT ON THAT. THAT'S STILL A NEW INVENTION. AND THAT'S  
23 WHAT THEY DID.

24 THEY HAD AN INSIGHT, A DISCOVERY. AND THEY CAME UP  
25 WITH -- THEY USED CONVENTIONAL TOOLS TO MAKE IT USEFUL TO OTHER

1 PEOPLE. AMPLIFY IT. LOOK FOR THE PATERNALLY INHERITED NUCLEIC  
2 ACIDS, SOME TINY FRACTION OF WHAT IS IN THAT SAMPLE. AND  
3 DISTINGUISH THEM FROM THE MOTHER, AND THEN YOU KNOW YOU'VE  
4 DETECTED FETAL NUCLEIC ACIDS.

5 THAT WAS AN INVENTION THAT HAS CHANGED THE WAY PEOPLE ARE  
6 PRACTICING MEDICINE.

7 THE COURT: WELL, I THINK THERE'S REALLY NO QUESTION ABOUT  
8 THAT. THE DISCOVERY OF --

9 MR. MALECEK: SO, YOUR HONOR --

10 THE COURT: NO QUESTION ABOUT THAT.

11 MR. MALECEK: I AGREE. THIS 101 JURISPRUDENCE IS  
12 DIFFICULT TO TACKLE. JUDGE RADER IS MAKING FUN OF IT HIMSELF  
13 AS WRITES AN OPINION, AND THEN WRITES A SEPARATE NOTE THAT SAYS  
14 HE DOESN'T LIKE IT, OKAY?

15 THEY ARE THE BOSSES, AND THEY ARE STRUGGLING WITH IT.  
16 RIGHT?

17 BUT THEY HAVE GIVEN US -- THERE ARE SOME PLACES THAT WE  
18 CAN RETURN TO AND BE COMFORTABLE. MYRIAD GIVES YOU THREE  
19 CLAIMS AND SAYS ONE IS INVALID, AND TWO ARE VALID.

20 I URGE THE COURT TO COMPARE THE NATURE OF THE CLAIMS THAT  
21 ARE INVALID TO THOSE THAT ARE VALID.

22 THANK YOU.

23 THE COURT: THANK YOU.

24 MR. GINDLER: BRIEFLY. THAT'S ALL I NEED.

25 SEQUENOM'S COUNSEL POINTS TO THREE ARTICLES FROM OVER A

1 DECADE AFTER THE PATENT APPLICATION THAT USE NEXT GENERATION  
2 SEQUENCING TO DETECT FETAL DNA, EITHER IN WHOLE BLOOD OR  
3 WITHOUT AMPLIFICATION.

4 WHY DID IT TAKE A DECADE? BECAUSE THE PATENT WAS DONE  
5 USING THE CONVENTIONAL TECHNIQUES. HOW DOES THIS TELL YOU  
6 WHETHER OR NOT THE CLAIM COVERS TOO MUCH AND IS USING THE  
7 ENTIRE NATURAL PHENOMENON?

8 THAT'S HOW YOU TELL. IT'S BEST TO START WITH THE CLAIM  
9 LANGUAGE. AND LET'S LOOK AT CLAIM ONE, WHICH EVERYONE HAS BEEN  
10 USING AS THE REPRESENTATIVE CLAIM. AND SEQUENOM HAS NOT  
11 POINTED TO ANY LIMITATIONS FROM ANY OTHER CLAIMS AS BEING THE  
12 BASIS OF FINDING PATENTABLE SUBJECT MATTER.

13 AND WHAT I WANT TO DO IS LOOK AT THE CLAIM RIGHT BEFORE  
14 THE PATENT OFFICE REQUIRED THE ADDITION OF THE AMPLIFICATION  
15 STEP.

16 REMEMBER, THE APPLICANTS WERE SET TO GET THEIR PATENT, AND  
17 THEN THE EXAMINER CALLED THEM AND SAID:

18 "I THINK YOU NEED TO ADD AMPLIFICATION."

19 SO THAT CLAIM WOULD READ AS FOLLOWS:

20 "A METHOD OF DETECTING A PATERNALLY INHERITED NUCLEIC  
21 ACID OF FETAL ORIGIN PERFORMED ON A MATERNAL SERUM OR  
22 PLASMA SAMPLE FROM A PREGNANT FEMALE WHICH METHOD  
23 COMPRISES DETECTING THE PRESENCE OF A PATERNALLY  
24 INHERITED NUCLEIC ACID OF FETAL ORIGIN IN THE SAMPLE."  
25 IT IS ENTIRELY CIRCULAR. IT DOESN'T TELL YOU ANYTHING



1 ABOUT THE METHOD OF DETECTION. WHY? BECAUSE, AS DR. LO TOLD  
2 THE PATENT OFFICE, EVERYONE KNOWS THE WAY TO DETECT NUCLEIC  
3 ACIDS, CELL-FREE NUCLEIC ACIDS IN SERUM OR PLASMA. I DIDN'T  
4 FIGURE OUT THAT ONE. HE DIDN'T CLAIM A PARTICULAR UNIQUE WAY  
5 OF DOING IT.

6 AND THE ONLY THING THAT GOT ADDED HERE WAS THE  
7 AMPLIFICATION STEP, WHICH EVERYONE AGREES WAS INVENTED A REALLY  
8 LONG TIME AGO. AND THE AMPLIFICATION STEP WAS ADDED ONLY  
9 BECAUSE THE PATENT OFFICE MADE THE APPLICANTS ADD IT AT THE  
10 LAST STAGE.

11 THEY HAVE NEVER POINTED TO THE AMPLIFICATION STEP AS:

12 "THIS IS WHAT MAKES MY PROCESS NOVEL," OR POINTED TO  
13 SOMETHING ABOUT THEIR DETECTION METHOD THAT MAKES THE STEP  
14 NOVEL.

15 THE CLAIM IS ENTIRELY CIRCULAR. IT'S JUST GO AND DETECT  
16 PATERNALLY INHERITED FETAL NUCLEIC ACID, BECAUSE WE FOUND IT.  
17 THAT PATENT IS NOT VALID. IT DOES NOT CLAIM SUBJECT MATTER.

18 YOU HEARD SEQUENOM'S COUNSEL EXPRESSLY STATE THAT THEY  
19 USED HIS WORDS "CONVENTIONAL TECHNIQUES." HIS WORDS. "KNOWN  
20 METHODS" TO FIND THIS.

21 SERUM OR PLASMA, THIS IS PART OF BLOOD. IT'S SOMETHING  
22 WHICH IS FOUND IN NATURE. PEOPLE AREN'T BUILDING SERUM OR  
23 PLASMA. THIS IS PART OF WHO WE ARE. THEY WEREN'T LOOKING IN  
24 SOMETHING WHICH THEY CREATED A NEW CONSTRUCT. THIS IS, AGAIN,  
25 A NATURAL PHENOMENON.

1 AND THEY LOOKED AT A PLACE WHERE PEOPLE HAD LOOKED BEFORE.  
2 THE FACT THAT THIS IS DISCUSSED IN PEER-REVIEWED LITERATURE  
3 THAT IS SIMPLY AN INDICATION, ARGUMENT BY SEQUENOM'S COUNSEL  
4 THAT THIS REALLY WAS NEW. NO ONE REALLY HAD DISCOVERED THIS  
5 BEFORE.

6 IF YOU ASSUME THAT'S TRUE, JUST FOR THE SAKE OF THIS  
7 ARGUMENT, IT DOESN'T SOLVE THE PROBLEM. BECAUSE, REMEMBER, YOU  
8 HAVE TO HAVE AN INVENTIVE CONCEPT WHICH IS SEPARATE AND APART  
9 FROM THE NATURAL PHENOMENON. THE INVENTIVE CONCEPT LANGUAGE  
10 SEQUENOM'S COUNSEL SAID COMES FROM JUDGE LOURIE.

11 NO, IT DOESN'T. IT ACTUALLY IS THE LANGUAGE WHICH  
12 ORIGINATED IN PARKER VERSUS FLOOK. THAT'S THE LANGUAGE I READ  
13 TO YOU AND REPEATED AGAIN IN MAYO.

14 YOU HAVE TO ASSESS THAT INVENTIVE CONCEPT WITHOUT  
15 REFERENCE TO THE NEW DISCOVERY, OTHERWISE EVERY USE OF A NEW  
16 DISCOVERY BECOMES PATENTABLE.

17 BECAUSE YOU COULD ALWAYS SAY -- YOU COULD ALWAYS SAY THAT  
18 IT'S A NEW USE.

19 COUNSEL ALSO READ TO YOU THAT SECOND PARAGRAPH ABOUT NEW  
20 APPLICATIONS OF KNOWLEDGE. WHERE'S THE NEW APPLICATION OF  
21 KNOWLEDGE HERE? I JUST READ YOU A CIRCULAR PATENT CLAIM THAT  
22 TALKS ABOUT THE METHOD OF DETECTING PATERNALLY INHERITED FETAL  
23 NUCLEIC ACID WHICH COMPRISES THE STEPS OF DETECTING PATERNALLY  
24 INHERITED FETAL NUCLEIC ACID OF FETAL ORIGIN, WITH AN  
25 APPLICATION STEP THROWN IN FOR GOOD MEASURE.

1 ONE FINAL POINT. SEQUENOM HAS REFERRED TO CLAIM 21 OF THE  
2 '441 PATENT. THE THIRD CLAIM, HE SAYS, THAT THE COURT SAID WAS  
3 OKAY.

4 I WOULD INVITE THE COURT TO READ THE DISTRICT COURT  
5 DECISION IN MYRIAD, THE FEDERAL CIRCUIT DECISION IN MYRIAD AND  
6 THE U.S. SUPREME COURT DECISION IN MYRIAD AND IDENTIFY THE  
7 DISCUSSION OF CLAIM 21.

8 THERE IS NONE. IT'S NOT EVEN QUOTED IN ANY OF THE  
9 OPINIONS. IT WASN'T CHALLENGED.

10 CLAIM 21 IS A CLAIM TO THE METHOD OF DETECTING AN  
11 ALTERATION IN THE BRCA1 GENE. WITHOUT ANY SUPPORT OF ANY KIND  
12 ANYWHERE, SEQUENOM SAYS THAT CLAIM INVOKES A CONVENTIONAL  
13 METHOD.

14 THEY JUST MADE THAT UP. THERE IS NO DISCUSSION OF THAT IN  
15 THE OPINION. IT TALKS -- THAT CLAIM TALKS ABOUT USING A BRCA1  
16 GENE PROBE. IS THAT NEW AND NOVEL IN THE USE OF THAT IN A  
17 PROCESS UNCONVENTIONAL?

18 I'M GUESSING THAT SINCE NO ONE CHALLENGED THAT CLAIM IT  
19 WAS NOT EVEN AT ISSUE IN THE CASE.

20 I'M GOING TO GUESS THERE'S SOMETHING DIFFERENT ABOUT THAT.  
21 BUT TO SAY THAT THE FEDERAL CIRCUIT APPROVINGLY DECIDED THAT  
22 CLAIM WAS VALID? IT WAS NEVER CHALLENGED, NEVER DISCUSSED, NOT  
23 QUOTED. WE DON'T KNOW A THING ABOUT CLAIM 21 EXCEPT THAT IT  
24 WASN'T PART OF THE CASE.

25 AND TO SUGGEST THAT THE MYRIAD COURT UPHELD THAT CLAIM?

1 WHAT MYRIAD SAID IS THAT A NATURAL -- AN ARTIFICIAL CONSTRUCT  
2 MADE IN THE LABORATORY CDNA IS PATENTABLE. AND THAT THE  
3 ISOLATED GENE IS NOT PATENTABLE.

4 AND THEY TOLD US ONE MORE THING AT THE END: IF THEY HAD  
5 USED A PROCESS TO FIND THAT GENE THAT WAS DIFFERENT MAYBE THAT  
6 WOULD HAVE BEEN PATENTABLE. BUT THEY USED A CONVENTIONAL  
7 TECHNIQUE. USING THE EXACT SAME LANGUAGE THEY USED IN MAYO.

8 WHAT DOES THAT TELL US ABOUT THE SUPREME COURT'S VIEW ON  
9 USING A CONVENTIONAL TECHNIQUE TO IDENTIFY THE LOCATION OF A  
10 NEW GENE?

11 IT'S NOT PATENTABLE.

12 THANK YOU.

13 THE COURT: OKAY. THANK YOU.

14 THANK YOU VERY MUCH. THE MATTER WILL BE SUBMITTED.

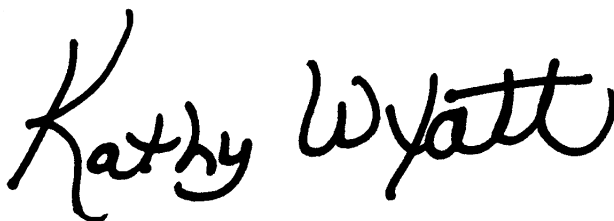
15 (THEREUPON, THIS HEARING WAS CONCLUDED.)

16 STENOGRAPHY CERTIFICATION

17 "I CERTIFY THAT THE FOREGOING IS A CORRECT  
18 TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE  
19 ABOVE-ENTITLED MATTER."

OCTOBER 28, 2013

KATHERINE WYATT

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